SEP 2 4 2004

K041925

510(k) Summary

Submitter:	Zimmer Spine, Inc. 7375 Bush Lake Road Minneapolis, Minnesota 55439
Date Prepared:	July 15, 2004
Contact:	Kristin Jans Manager, Regulatory Affairs
Proprietary Name:	ST360™ Spinal Fixation System
Common Name:	Rod, hook, and screw spinal instrumentation
Device Product Code & Classification:	Class III; MNI, MNH, KWP, NKB
Predicate Device:	ST360™ Spinal Fixation System (formerly Cadence) (K022374)

Device Description:
The ST360™ Spinal Fixation System is a temporary implant system used to correct spinal deformity and to facilitate the biological process of spinal fusion. This system is intended for posterior use in the thoracic, lumbar, and sacral areas of the spine. Implants in this system consist of hooks and/or screws connected to rods that are intended to be removed after solid fusion has occurred. The system includes polyaxial screws of varying diameters and lengths; fixed screws of varying diameters and lengths; rods in varying lengths; hooks in varying designs; and transverse connectors in the various configurations of fixed, adjustable, variable angle offset and axial. All implant components are either top loading and top tightening. The implants in this system are manufactured from titanium alloy (Ti-6Al-4V) that conforms to ASTM F-136.

Intended Use:
The ST360™ Spinal System is intended for posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; deformities (i.e., scoliosis, kyphosis, and/or lordosis), tumor; pseudoarthrosis, and failed previous fusion. Pedicle screw fixation is limited to skeletally mature patients.

Statement of Technological Comparison:
Mechanical testing was carried out according to ASTM F 1717 and ASTM F 1798 to validate the modifications to the ST360™ Spinal Fixation System. The testing demonstrated substantially equivalent mechanical properties to the previously cleared Silhouette™ Spinal Fixation System and ST360™ Spinal Fixation System components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 4 2004

Ms. Kristin Jans, RAC
Manager, Regulatory Affairs
Zimmer Spine, Inc.
7375 Bush Lake Road
Minneapolis, Minnesota 55439-2027

Re: K041925
Trade/Device Name: ST360™ Spinal Fixation System
Regulation Number: 21 CFR 888.3050, 888.3070
Regulation Name: Spinal interlaminal fixation orthosis; pedicle screw spinal system
Regulatory Class: Class III
Product Code: KWP, MNH, MNI, NKB
Dated: June 14, 2004
Received: June 15, 2004

Dear Ms. Jans:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

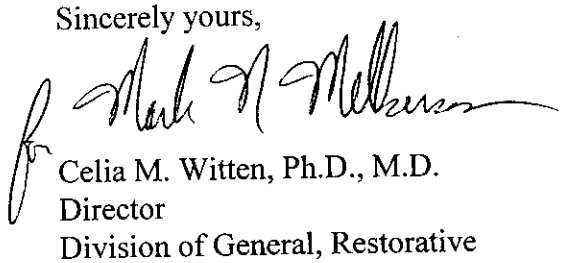
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number : K041925

Device Name: ST360°™ Spinal Fixation System

The ST360°™ Spinal System is intended for posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; deformities (i.e., scoliosis, kyphosis, and/or lordosis), tumor; pseudoarthrosis, and failed previous fusion. Pedicle screw fixation is limited to skeletally mature patients.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041925